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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,265	07/27/2001	Ramani S. Wonderling	IM-5	7797

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HESKA CORPORATION
INTELLECTUAL PROPERTY DEPT.
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FORT COLLINS, CO 80525

EXAMINER

MARTINELL, JAMES

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 08/26/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/917,265

Applicant(s)

WONDERLING ET AL.

Examiner

James Martinell

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22,23 and 28-37 is/are allowed.
- 6) ☒ Claim(s) 24-27 and 38-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1631

The amendment filed June 6, 2003 has been entered. That amendment omitted a claim 24, so the claims have been renumbered (see 37 CFR § 1.126). Each of applicants' claims numbered 25 through 41 has been renumbered as 24 through 40, respectively. In addition, newly renumbered claim 25 now depends from newly renumbered claim 24, newly renumbered claim 29 depends from newly renumbered claim 28, newly renumbered claim 38 depends from newly renumbered claim 37, newly renumbered claim 39 depends from newly renumbered claim 38, and newly renumbered claim 40 depends from newly renumbered claim 37.

Applicants' arguments in connection with the requirement for restriction among the several sequences claimed and mentioned in the instant claims is persuasive. Thus, all of claims 22-40 are examined.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-27 and 38-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, and incomplete.

- (a) The recitation of "selectively binding" (claim 25) is vague, indefinite, and incomplete because selective binding depends upon the presence of other binding molecules present in a binding reaction. The other molecules are not mentioned or described in the claim.
- (b) Claim 25 is vague, indefinite, and incomplete in its description of the nucleic acid molecules.
- (c) The recitation of "allelic variant" (claims 26, 27, and 38-40) is vague and indefinite because the instant application gives no information as to the genetic locus of any of the

Art Unit: 1631

DNAs mentioned in the application. Since alleles occupy the same genetic locus, such information is essential to the claimed invention.

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant application does not provide an adequate written description of the invention in that the claim describes the DNAs in the claim only in relation to the functions of the polypeptides encoded by the DNAs.

Claims 24, 25, and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for constructs containing DNAs that encode specifically defined amino acid sequences, does not reasonably provide enablement for constructs containing DNAs that encode amino acid sequences with less than 100% sequence similarity to the defined sequences mentioned in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims require DNAs that encode amino acid sequences that have at least 90% sequence similarity to certain amino acid sequences disclosed in the application. The instant application does not provide adequate guidance to those of skill in the art for the production of active embodiments given the astronomical number of possible combinations of sequences embraced by the claims. Thus, one of skill in the art would be compelled to perform undue experimentation to arrive at a reasonable number of embodiments that work as claimed and disclosed. Without specific guidance as to which of the astronomically large number of polypeptides mentioned in the claims, one of skill in the art would be obliged to perform undue experimentation to determine which variants might have activity and/or use. The Court of Appeals for the Federal Circuit found that claims reciting polypeptides with multiple amino acid substitutions were broader than the enabling disclosure. See (*Amgen v. Chugai* (18 USPQ2d 1016, Fed. Cir. 1991)).

Claims 22, 23, and 28-37 are allowable over the prior art of record.

Art Unit: 1631

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (703) 308-0296. The fax phone number for Examiner Martinell's desktop workstation is (703) 746-5162. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

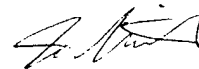
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 305-4028.

Art Unit: 1631

PLEASE NOTE THE NEW FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



**James Martinell, Ph.D.
Primary Examiner
Art Unit 1631**